

worse adverse effect in relation to the study arm and the concomitant medication classes/medications of interest.

Results The dose of CBD self-selected by participants was not related to opioid use or medications including benzodiazepines and antipsychotics. The likelihood of developing an adverse effect whilst on study or when taking specific medications was not increased by the use of CBD. There was a suggestion that paracetamol could be protective against the side-effects of CBD but this was not supported by all analyses.

Discussion Although there is potential for CBD to interact with multiple medications, the findings of this sub-study suggest that concerns regarding clinically significant drug interactions with CBD may be unfounded.

P-15 CLINICAL STUDIES OF MEDICINAL CANNABIS IN PALLIATIVE CARE – THE DEVELOPMENT OF A RESEARCH PROGRAM

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Background Medicinal Cannabis (MC) was legalised in Australia in 2016 for a range of indications including palliative care, despite a lack of research evidence. Patients with advanced cancer in the community commonly access cannabis aiming to improve their symptoms. Following the award of grants from the NHMRC – Medical Research Future Fund in 2018 and 2020, we have developed a medicinal cannabis research program.

Objectives To define the role (if any) of cannabinoids in patients with symptoms from advanced cancer.

To conduct robust phase three clinical trials to contribute to the evidence base for medicinal cannabis prescribing in Australia.

Methods Develop and complete a pilot study to test the feasibility of a larger RCT with an MC product in an advanced cancer patient population and develop phase 3 MC trials 1, 2 and 3 of different products and concentrations. Explore qualitative studies around patient use and views of MC products in our community and conduct sub studies testing the anti-inflammatory properties of cannabinoids. Investigate the detection of tetrahydrocannabinol (THC) medicinal products in relation to motor vehicle driving and real-world implications. Conduct post trial long term surveillance of marketed products using the authorised prescriber scheme.

Results In the pilot study 86% of recruits completed the primary outcome with 46% meeting the definition of response. The study drug was well tolerated. MedCan 1, a cannabidiol (CBD) versus placebo RCT (n=144), showed all components of the Edmonton Symptom Assessment Scale (ESAS) improved (fell) over time with no difference between arms. There was no detectable effect of CBD on quality of life, depression, or anxiety. Adverse events did not differ significantly between arms apart from dyspnoea that was more common with CBD. Most participants reported feeling better or much better at days 14 and 28. In MedCan 2, a (THC)/CBD 1:1 versus placebo RCT, the results showed no total ESAS difference

between arms. There was a significant difference in reduction in ESAS pain scores at day 14 (mean (SD) -1.41 (2.15) MC, -0.46 (2.82) placebo), $p = 0.04$ in favour of MC. Adverse events of special interest revealed an increased incidence of confusion, feeling high, and exaggerated sense of well-being in the MC arm. In a C-reactive protein sub study, we were unable to demonstrate an anti-inflammatory effect of CBD in cancer patients.

Discussion Medicinal cannabis is commonly used in the community by people with cancer to treat the associated troubling symptoms of their disease and treatment. Our trials have been designed to define the best and safest place for MC in supportive care. Our results have been included in systematic reviews, meta-analyses, and international guidelines. Health consumers have provided valuable input into the design of our trials and ongoing safety monitoring. Currently we have 15 publications with MedCan 3, MedCan Drive, MedCan Inflamm, MedCan Post trial, and two qualitative studies still in the recruitment phase. Our results will continue to inform policy and practice around MC prescribing both nationally and internationally.

P-16 BALANCING QUALITY OF LIFE AND MEDICAL FUTILITY: AN ETHICAL DILEMMA IN END STAGE RENAL DISEASE

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Decisions around dialysis withdrawal can be highly complex and challenging for patients, caregivers, and healthcare providers. There are various reasons why dialysis withdrawal may be considered, including access failure, acute medical complications, or chronic deterioration. Shared decision-making is recommended to align this decision with the patient and family's goals, values, and preferences.¹

However, problems can arise when there is a misalignment or disagreement between what the family/patient desires and what the medical team deems medically appropriate.

In this case, we discuss a 74-year-old woman with end-stage renal failure on intermittent haemodialysis. She lacks decision-making capacity and is bedbound and dependent in her activities of daily living due to her advanced dementia. Her recent medical deterioration and lack of access has made it difficult to continue haemodialysis. Despite the medical team's recommendation to withdraw dialysis, her main spokesperson, a close friend, does not agree and insists on pursuing further treatment. This presents an ethical dilemma - is it appropriate to persist with dialysis in this medically frail patient, at the spokesperson's insistence, when the treatment may not be medically appropriate or beneficial given her current state?

The Jonsen's 4 box ethical framework was used to consider the medical indications, patient preferences, quality of life, and contextual features to plan care in the patient's best interests in the absence of decision-making capacity.

REFERENCE

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